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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,441	03/04/2002	Peter B. Shimm	P 283392	4015
909	7590	01/07/2005	EXAMINER	
PILLSBURY WINTHROP, LLP				SZMAL, BRIAN SCOTT
P.O. BOX 10500				ART UNIT
MCLEAN, VA 22102				PAPER NUMBER
				3736

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

JA

Office Action Summary	Application No.	Applicant(s)
	10/086,441	SHIMM, PETER B.
	Examiner Brian Szmal	Art Unit 3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 October 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3,14,15,18-20 and 25-27 is/are rejected.
- 7) Claim(s) 4-13,16 and 17 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4-3-02</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

Election/Restrictions

1. Applicant's election with traverse of the restriction requirement mailed on September 27, 2004 in the reply filed on October 26, 2004 is acknowledged. The traversal is on the ground(s) that there would not be a serious burden placed upon the Examiner due to the alleged relation of Group I and Group II having a "hands-free syringe controller" and a "foot-actuated syringe controller", respectively. This is not found persuasive because Group I discloses the use of an electrical current generator to stimulate tissue in combination with the hands-free syringe controller, which is classified in Class 600, Subclass 554, whereas, Group II is classified in Class 128, Digest 1, or even in Class 604, Subclass 154. Therefore, due to the different areas of classification for Groups I and II, and the lack of a current generator for stimulating tissue within Group II, the restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claim 27 is objected to because of the following informalities: In line 1 of the claim, "actuation of first switch" should read as "actuation of the first switch" to be grammatically correct. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-3 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raymond et al (5,284,153) in view of Battiato et al (5,925,022).

Raymond et al disclose a means for locating a nerve and protecting nerves from injury during surgery and further disclose a needle adapted to be connected to a syringe having an anesthetic therein; an electric current generator operatively connected to the needle to selectively apply an electrical stimulus to the needle; a hands-free current generator operatively connected to the current generator, the current generator determining electrical characteristics, including at least an amperage of the electrical stimulus; and the current generator is foot-operated. See Column 3, lines 24-29, 36-38 and 52-56; Column 5, lines 59-68; Column 6, lines 1-2; and Column 17, lines 11-13.

Raymond et al, however fail to disclose a hands-free syringe controller adapted to be connected to the syringe to selectively aspirate the syringe to inject the anesthetic through the needle; the syringe controller comprises a foot pedal movably connected to the base, the foot pedal having compressed and uncompressed positions relative to the base; and the foot pedal is pivotally mounted to the base.

Battiato et al disclose a medical fluid injector and further disclose a hands-free syringe controller adapted to be connected to the syringe to selectively aspirate the syringe to inject the anesthetic through the needle; the syringe controller comprises a foot pedal movably connected to the base, the foot pedal having compressed and uncompressed

positions relative to the base; and the foot pedal is pivotally mounted to the base. See Column 5, lines 51-57; and Column 6, lines 2-10.

Since both Raymond et al and Battiato et al disclose means for injecting medical fluids during a medical procedure, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Raymond et al to include the use of a hands-free syringe controller, as per the teachings of Battiato et al, since it would provide a means of adequately providing a correct dosage of anesthetic to the located nerve during the procedure.

5. Claims 15 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raymond et al (5,284,153) and Battiato et al (5,925,022) as applied to claim 14 above, and further in view of Attaway (GB 2322744 A).

Raymond et al and Battiato et al, as discussed above, disclose means for locating nerves and delivering medical fluids to the patient, but fail to disclose first and second foot switches mounted to the base and operatively connected to the electric current generator, wherein actuation of the first foot switch increases the amperage and wherein actuation of the second foot switch decreases the amperage; each actuation of the first switch incrementally increases the amperage; each actuation of the second switch incrementally decreases the amperage; and continuous actuation of the first switch increases the amperage by more than one increment, and wherein continuous actuation of the second switch decreases the amperage by more than one increment. Attaway discloses a foot operated instrument and further discloses first and second foot switches mounted to the base and operatively connected to the electric current

generator, wherein actuation of the first foot switch increases the amperage and wherein actuation of the second foot switch decreases the amperage; each actuation of the first switch incrementally increases the amperage; each actuation of the second switch incrementally decreases the amperage; and continuous actuation of the first switch increases the amperage by more than one increment, and wherein continuous actuation of the second switch decreases the amperage by more than one increment.

See Abstract.

Since Raymond et al, Battiato et al and Attaway disclose means for using foot actuated devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Raymond et al and Battiato et al to include the use of a first switch to incrementally increase the current to the device and a second switch to incrementally decrease the current to the device, as per the teachings of Attaway, since it would provide a means to the physician to adjust the current to the device without using his/her hands during the procedure.

6. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raymond et al (5,284,153) and Battiato et al (5,925,022) as applied to claim 1 above, and further in view of Hill et al (6,449,507 B1).

Raymond et al and Battiato et al, as discussed above, disclose means for locating nerves and delivering medical fluids to the patient, but fail to disclose an amperage display operatively connected to the current generator, the amperage display being adapted to display the amperage being output by the generator; and a speaker

operatively connected to the current generator to call out audibly the amperage being output by the current generator.

Hill et al disclose a means for nerve stimulation prior to and during a medical procedure and further disclose an amperage display operatively connected to the current generator, the amperage display being adapted to display the amperage being output by the generator; and a speaker operatively connected to the current generator to call out audibly the amperage being output by the current generator. See Column 9, lines 29-32.

Since Raymond et al, Battiato et al and Hill et al disclose means for effecting medical procedures while stimulating nerves and injecting medical fluids, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Raymond et al and Battiato et al to include the use of a display or a speaker to audibly indicate the amperage being generated by the generator, as per the teachings of Hill et al, since it would provide a means of indicating to the operator the generated current through visual or audible means.

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raymond et al (5,284,153) and Battiato et al (5,925,022) as applied to claim 1 above, and further in view of Eggers et al (2003/0023285 A1).

Raymond et al and Battiato et al, as discussed above, disclose means for locating nerves and delivering medical fluids to the patient, but fail to disclose a light operatively connected to the current generator, the current generator and light being constructed such that the light flashes each time the electric stimulus is applied to the needle.

Eggers et al disclose a means of cutting about and into tissue and further disclose a light operatively connected to the current generator, the current generator and light being constructed such that the light flashes each time the electric stimulus is applied to the needle. See Paragraphs 0079, 0084 and 0108.

Since Raymond et al, Battiato et al and Eggers et al disclose means for effecting a medical procedure using hands-free actuated equipment, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Raymond et al and Battiato et al to include the use of a light for indicating when a stimulus is being applied to the needle, as per the teachings of Eggers et al, since it would provide a means of visually indicating to the operator when a stimulus is being applied to the probe.

Allowable Subject Matter

8. Claims 4-13, 16 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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